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Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

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MEMORANDUM

TO: Local Health Officers

FROM: Judy Monroe, MD
State Health Commissioner

DATE: May 6, 2009

RE: Distribution of Personal Protective Equipment

The purpose of this memorandum and the accompanying documents is to advise Local Health Officers and local health departments as to the distribution of personal protective equipment (PPE) from the Strategic National Stockpile and to communicate information regarding the Emergency Use Authorization issued by the Food & Drug Administration (FDA) covering certain N95 respirators.

AT THIS TIME, ALL PERSONAL PROTECTIVE EQUIPMENT RECEIVED FROM THE STATE SHOULD NOT BE USED OR FURTHER DISTRIBUTED, BUT SHOULD REMAIN SECURE AND STORED AT ROOM TEMPERATURE (BETWEEN 59 AND 86 DEGREES FAHRENHEIT). THE PERSONAL PROTECTIVE EQUIPMENT HAS BEEN DISTRIBUTED TO LOCAL HEALTH DEPARTMENTS FOR PRE-POSITIONING PURPOSES ONLY AND SHALL REMAIN SECURELY STORED UNTIL FURTHER ADVISEMENT FROM THE INDIANA STATE DEPARTMENT OF HEALTH HAS BEEN RECEIVED.

The following information and accompanying documents will assist you in planning for the future distribution and utilization of certain personal protective equipment, specifically the N95 respirators:

I. Emergency Use Authorization (EUA)

The FDA has authorized for the emergency use of certain personal respiratory protection devices deployed from the Strategic National Stockpile. The specific products covered are listed in the attached Fact Sheet and FDA-issued EUA authorization letter. The EUA authorizes the use, by the general public, of certain N95 respirators to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency involving H1N1 influenza.

The term "general public" is broad and includes people performing work-related duties. However, it should be noted that the authorization affects only the requirements applicable under the Federal Food, Drug, and Cosmetic Act. If respirators are used for people performing work-related duties, employers must still comply with the Occupational Safety and Health Administration's (OSHA) Respiratory Protection Standard, 29 CFR 1910.134.

The EUA provides that the N95 respirators are authorized to be made available to recipients when accompanied by the specified Fact Sheet. They may also be made available to recipients in the form (i.e. – with the packaging and labeling) in which they are customarily sold for use, as long as they are accompanied by the specified Fact Sheet.

Be advised that though state and local health departments may provide additional information relating to the emergency use of the identified N95 respirators that additional information must be consistent with, and may NOT exceed, the terms of the letter of authorization.

If states and local jurisdictions do not distribute or utilize the specified N95 respirators in accordance with the scope and conditions of the EUA, liability protections afforded by the Public Readiness and Emergency Preparedness (PREP) Act may be affected.

Additional information is available online at: <http://www.cdc.gov/h1n1flu/eua/>.

If you have further questions about these requirements, please contact Jennifer Bruner by e-mail (jbruner@isdh.IN.gov) or by phone (317.234.2818).

Accompanying Documents:

- EUA Amended Letter – N95
- EUA Fact Sheet – N95
- CDC N95 Instructions